

Rule
1.126

42
43. The composition of claim 36, further comprising a second cell comprising a nucleic acid encoding a GM-CSF. - -

REMARKS

The instant application relates to novel prostate tumor antigens, see the Figures. The antigens, under normal circumstances, do not elicit a humoral response. However, when administered with a proliferation-incompetent cell and a cytokine, the patient raises a humoral response to the particular prostate tumor antigen.

I. On page 2 of the Office Action, claims 23-34 were rejected under 35 U.S.C. § 112, first paragraph for an alleged want of enablement.

The rejection is traversed for the following reasons.

The use of a cytokine-assisted cancer antigen vaccine is in practice in clinical trials. The attention of the Examiner is directed to Simons et al. and Soiffer et al., of record. Those papers document obtaining a therapeutic benefit with the use of a cancer antigen and a cytokine. Thus, by analogy, the instant invention also is enabled.

The Spitler and Ezzel references were raised by the Examiner to support the position that the art of cancer vaccines is unpredictable. Both references were published in 1995 and in fact, predicted success in cancer vaccines. The success predicted by the Simons et al. and Soiffer et al. references is further supported by the various GVAX® clinical trials such as those described in the examples of the instant specification.

Thus, the claimed invention clearly is enabled. The instant specification, in view of the state of the art, teaches how to make and how to use the invention of interest. The *prima facie* case of non-enablement has not been made and thus the rejection can be removed.

II. In item 2 on page 2 of the Office Action, claims 23-34 were rejected under 35 U.S.C. § 102(b) over the Dranoff et al. patent.

The rejection is traversed for the following reasons.

As recited in base claim 36, the instant invention relates to prostate tumor antigens which alone do not stimulate a humoral response, but when administered with a proliferation-incompetent cell in the presence of a cytokine, are effectively immunogenic and the host responds to that prostate tumor antigen, in part, by generating antibody thereto.

The Dranoff et al. patent does not teach the claimed invention, such as the particular prostate tumor antigens and thus, anticipation does not lie. Accordingly, withdrawal of the rejection is in order.

III. At the bottom of page 2 of the Office Action, claims 23-29 and 30-34 were rejected under 35 U.S.C. § 102(b) over WO98/04282.

The rejection is traversed for the following reasons.

As taught hereinabove, the instant invention relates to particular prostate tumor antigens to which the host does not react but for the concomitant administration of a proliferation-incompetent cell and cytokine.

The '282 application does not teach the particularly claimed prostate tumor antigens. Therefore, the '282 application does not teach the claimed invention. Accordingly, anticipation does not exist and the rejection should be removed.

IV. On page 3 of the Office Action, claims 23-34 were rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of written description. The Examiner stated the specification does not describe the particular antigens of defined molecular weight. The Examiner indicated the rejection would be overcome if the claims indicate particular tissues associated with particular antigens.

The rejection is traversed for the following reasons.

The claims recite particular prostate tumor antigens. The Figures of the instant application depict Western blots wherein specific antisera bind to prostate tumor antigens that were not detectable prior to exposure of the host to proliferation-incompetent prostate tumor cells in the presence of a cytokine. The control antisera were obtained from the very patients prior to exposure to the cytokine and vaccine, and specific antibody did not exist at that time.

Clearly the instant specification teaches the particular prostate tumor antigens that generate an immune response thereto under the particular conditions as recited in the claims.

There is a clear, thorough and discriminating description of the claimed invention in the instant specification. An artisan would well recognize that the inventors were in possession of the claimed invention on reading the instant specification.

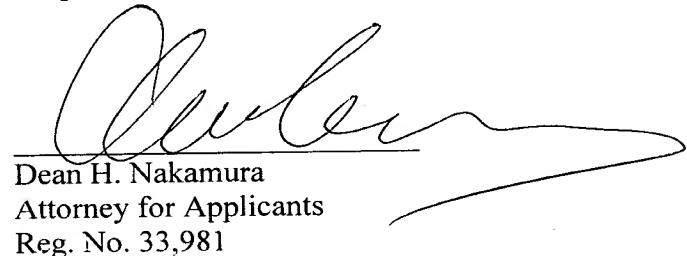
Hence, the statutory requirements of 35 U.S.C. § 112, first paragraph being met and written description being present, the rejection can be removed.

CONCLUSION

The instant application is in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections and early indication of allowance are solicited earnestly.

If any questions remain unresolved, the Examiner is urged to contact the undersigned at the local exchange noted hereinbelow. The Commissioner hereby is authorized to charge or to credit any shortage or surplus to Deposit Account No. 18-2220.

Respectfully submitted,



Dean H. Nakamura
Attorney for Applicants
Reg. No. 33,981

Roylance, Abrams, Berdo
& Goodman L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036-2680
(202) 659-9076

Dated: 4 December 2002